Resource 3

QUESTIONS AND ANSWERS

SAMPLE COLLECTION

1. **Question:** If a sample is collected on a Friday but not picked up by Federal Express on that day, and if the next scheduled pick up is Monday, can the sample be kept in the cooler or freezer until Monday and then shipped?

   Answer: Inspection program personnel should try to avoid holding samples over the weekend whenever possible because the establishment would most likely be holding the sampled lot. If Federal Express cannot pick up the sample on the day of collection, inspection program personnel can refrigerate or freeze the sample until it can be picked up. However, inspection program personnel should not hold samples for more than three days (i.e., Friday to Monday) prior to shipping.

2. **Question:** If inspection program personnel already have sample requests forms issued under FSIS 10,240.3 when FSIS 10,240.4 became effective, what should they do?

   Answer: Inspection program personnel should collect samples according to the timeframes identified on the sample request forms and regardless of whether the form was issued before or after implementation of FSIS Directive 10,240.4.

3. **Question:** The interim final rule requires that an establishment define the size of the sampling site. How does one go about defining a standard size when the equipment to be sampled will vary widely and will likely require differing sample sizes to be most effective?

   Answer: In determining the sample size for a FCS, the establishment must take into account that the FCS on any individual piece of equipment will vary. For this reason, the establishment written program must provide clear directions on how samples will be taken depending on the available FCS. For example, for equipment with FCS less than 1 square foot (12 in. X12 in.), the entire surface should be sampled. For FCS larger than 1 square foot, a contiguous area of at least that size should be sampled.

4. **Question:** Would USDA test the same RTE sites as the plant?

   Answer: Yes. FSIS may test the same food contact surface sites as the plant does.

5. **Question:** In a small plant there is no line. What is a line?

   Answer: A line refers the flow of product during production. This includes whatever equipment is handling RTE product.

6. **Question:** When should a plant take an environmental swab for Lm?

   Answer: An environmental sample taken after three hours of the start of operations would provide the most efficient time to detect contamination with *L. monocytogenes* or an indicator organism.

7. **Question:** Can testing for ATP be used as testing for RTE equipment?

   Answer: ATP testing can be used in the sanitation program for verifying effectiveness of cleaning and sanitizing during pre-op. However, to verify the effectiveness of your controls for *L. monocytogenes*, testing for *L. monocytogenes* or its indicators is used.

8. **Answer:** Is drain or ceiling considered food contact surfaces?

   Question: No.

9. **Question:** Can a plant produce smaller volume of product on the day they are to test for *L. monocytogenes*?

   Answer: This is up to the plant. The plant must explain why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or indicator organisms is maintained.

10. **Question:** With different pieces of equipment, can plant have 5 sampling sites?

    Answer: The number of sites sampled depends on the type of equipment, processing operation, and plant layout. Sampling sites are not limited to only food contact surfaces but include environmental samples (e.g., gloves, switches, floors, drains, etc.)

SAMPLE RESULTS

11. **Question:** If an establishment delivered product from a sampled lot to a customer but retrieved all of it before the report of the FSIS sample result, will the product be deemed to have been shipped?

    Answer: Yes, once an establishment completes its pre-shipment record review, the product is considered “eligible for shipment or “shipped.” Upon

report of a positive result, establishments are expected to prevent product from entering commerce in accordance with sections 9 CFR 417.3(a)(4) or (b)(3)of the regulations and to process it in a manner that will make it no longer adulterated. Product adulterated with a pathogen that is not processed in such a manner will be condemned. Inspection program personnel are not to take any regulatory control actions unless the establishment fails to control product as specified in 9 CFR 417.3(a)(4) or (b)(3).

12. **Question:** If a product or food contact surface sample tests positive for a pathogen, what is the status of product(s) produced on days subsequent to the day the sample was collected?

Answer: In general, FSIS does not consider product that is produced on days subsequent to the day of sampling and that is coded differently from the sampled lot to be represented by the sample, and under most circumstances, the product is not subject to retention, detention, or voluntary recall. A positive sample does call into question the adequacy of an establishment's process for producing safe product. For deli and hotdog products in Alternative 3, the establishment must verify the effectiveness of the corrective actions by conducting follow-up testing. Upon report of a positive sample, inspection program personnel will perform the appropriate HACCP 02 procedure on the product's HACCP plan, and an 01B01 and an 01C01 procedure on the establishment's Sanitation SOPs covering the time period from when the sample was collected to the present. If, in performing these procedures, inspection program personnel find that the establishment shipped adulterated product other than the sampled lot, this additional product will be subject to detention, voluntary recall, or seizure. For example, if inspection program personnel find that the establishment failed to meet the critical limit at the cooking CCP and took no corrective action on subsequent lots, all product affected by this failure is subject to retention, detention, voluntary recall, or seizure.

13. **Question:** The Compliance Guidance indicates that for *Listeria* spp. testing the methodology should employ enrichment, and that screening should be conducted using immunoassay, nucleic acid assay or equivalent *Listeria* spp. specific technology. Does this mean that cultural methods such as enrichment, followed by plating on MOX, followed by additional cultural identification steps that stop short of species identification would not be acceptable?

Answer: As indicated in the guidelines, any methodology used by a regulatory body or validated by a recognized body is acceptable. Other methods that have been validated or recognized in peer-reviewed articles would be acceptable.

14. **Question:** Can an establishment test in-house for L. monocytogenes?

Answer: Yes. Testing for L. monocytogenes can be used to verify the effectiveness of the controls used. The method should be AOAC approved or equivalent to FSIS testing procedures. The FSIS methods can be found in the Microbiology Laboratory Guidebook - http://www.fsis.usda.gov/OPHS/microlab/mlgbook.htm.

15. **Question:** Does a sample test result that is positive for *Listeria* spp. or *Listeria*- like organisms indicate that the product is adulterated?

Answer: No. However, FSIS considers a finding of *Listeria* spp. or *Listeria* – like organisms on product or a food contact surface to be an indication of the potential presence of the pathogen, and that the process may not be appropriately controlled. The establishment should take corrective actions as specified in its control program. This may include taking new or additional verification samples of product and of the food contact surface.

16. **Question:** If a RTE product tested by FSIS is found positive for a pathogen, is the HACCP plan automatically inadequate, and should the inspector immediately take a withholding action?

Answer: According to 417.6(e). the HACCP plan may be found inadequate. In determining whether the HACCP plan is inadequate, the Agency will take into account all available information and consider the entire situation before making a determination of HACCP plan inadequacy. The cause and significance of a positive result varies from case to case depending on the circumstances of processing involved, and the pathogen found. FSIS will consider whether some or all products produced under the same or a substantially similar HACCP plan are affected, whether there have been other incidents of product contamination with the pathogen, and whether incidents of product contamination have been persistent or recurring. Establishments are required to take corrective and preventive actions in accordance with 9 CFR 417.3.

Product that tests positive for *Listeria monocytogenes* or other pathogens is considered adulterated and must be condemned or reworked according to the establishment's HACCP plan or corrective and preventive action arrived at under 9 CFR 417.3(b). When considering a withholding action, inspection program personnel will follow the procedures in FSIS Directive 5000.1, Chapter IV, Rules of Practice Part III, and 9 CFR Part 500. If the IIC determines, on the basis of available information, that the establishment is continuing to produce and ship product that may be injurious to health, the IIC should withhold the marks of inspection and

inform the DO.

17. **Question:** If a food contact surface tests positive for *L. monocytogenes*, will the plant have the opportunity to test the product involved?

    Answer: USDA would consider this product adulterated and would request a voluntary recall. The establishment can test product at a frequency and with a sampling method that provides a level of statistical confidence that the product is not adulterated with *L. monocytogenes*.

18. **Question:** What if plant gets a positive environmental sample in a floor drain?

    Answer: An environmental sample positive for *L. monocytogenes* or indicator organisms should initiate intensified cleaning and sanitizing. Keeping up with plant sanitation is one way to control *L. monocytogene*s contamination. Testing of non-contact surfaces should be included in the SSOP/HACCP plans. Hold and test procedures apply only to food contact surface and product testing.

19. **Question:** Are we required to hold lots when RTE testing food contact surfaces?

    Answer: Establishments producing products under Alternative 2, using antimicrobial agents or processes, or 3 are required to identify the conditions under which they will implement hold and test procedures. For hot dogs and deli meats in Alternative 3, on 2nd positive test of a food contact surface, the establishment must hold and test product lots that may have become contaminated. When FSIS takes samples for testing, establishments decide if they want to hold products.

20. **Question:** What is meant by "the post-lethality processing environment," and how will sampling and testing of this environment come into play following a positive test result for *L. monocytogenes* or *Listeria* spp. on a product contact surface?

    Answer: The post-lethality processing environment encompasses all areas an exposed product goes through from the end of the lethality step to the time it is packaged. Should a post-lethality processing environment contact surface test positive, the agency would expect that the establishment would investigate the potential source of the positive finding and where that source is located, then take corrective actions to eliminate the source and verify the effectiveness of the corrective actions. In certain situations, the source of *Listeria* may be the specific equipment that tested positive, such as a slicer. In other situations, such as a positive on a conveyor belt, the source may be a different location than the

area tested.

21. **Question:** The use of the term “indicator organism” throughout the document seems to be in conflict with the definition of “indicator organism” as defined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). The rule links the “indicator organism” to *L. monocytogenes*; in this case, is the term “index organism” more appropriate?

    Answer: The subsequent Directive and related publications will use the appropriate terminology as defined by the NACMCF. However, FSIS does believe that the term “indicator organism” is appropriate because a condition or state of sanitary control is being addressed.

22. **Question:** If an establishment that produces hotdog or deli products under Alternative 3 tests for indicator organisms and has a second positive result for *Listeria* spp. or *Listeria* -like organisms does this mean that the establishment’s control and testing programs that are incorporated into their HACCP plan, Sanitation SOPs, or prerequisite programs are automatically invalid?

    Answer: No. FSIS will take into consideration how the establishment responds to the positives, the type of intensified testing the establishment conducts, and the conditions that may have led to the second positive. In some cases, the second positive may have occurred from lack of proper execution of control programs, and in other cases may indicate a design problem. In this case, establishments that choose Alternatives 1 and 2 or Alternative 3 for non-deli and non-hotdog products must take corrective actions as specified in their sanitation and testing programs contained in their HACCP plan, Sanitation SOP or prerequisite programs. In addition, establishments must follow their hold-and- test program.

    Establishments that choose Alternative 3 for deli and hotdog products are to hold product and test for *L. monocytogenes,* take the corrective actions specified in their sanitation and testing programs, and test food contact surfaces until the food contact surface testing indicates that problems have been corrected. The lots of product produced after the second (follow-up) food contact surface positive test must be held until the problems that caused the positive test results have been corrected. (See ‘Hold and Test Scenario’ in the Compliance Guidelines.)

23. **Question:** Can establishments use product that tested positive for a pathogen as “rework?” Are there special restrictions?

    Answer: The regulations do not prohibit the use of product that tested positive for a pathogen as “rework.” An establishment is expected to

address the use of such product in its HACCP plan. The plan should address any hazards presented by the practice, such as the potential hazard of increased tolerance of bacteria that survived a "kill" step. If such product is reworked routinely, then critical limits and CCPs need to account for any additional potential hazards. If contaminated product is reworked only occasionally, the plan may only need to address the procedures, critical limits, and CCPs to be met when lots containing rework are processed. When product that tested positive is identified after it has left an establishment, it may be moved under control to an establishment where it can be further processed.

24. **Question:** Can establishment use USDA results from RTE samples for their benefit?

Answer: No. FSIS does not routinely take product or environmental samples. Product sampling is not conducted at a level to ensure the product is free of *L. monocytogenes* or other foodborne pathogens. Intensified verification sampling for *L. monocytogenes* is conducted in response to a problem at, or originating from, the establishment.

FOLLOW-UP OR INTENSIFIED SAMPLING

25. **Question:** During follow-up verification sampling that may be scheduled from headquarters, must the samples be collected on consecutive production days?

Answer: The sample request forms should come with a note that instructs the inspection program employee to collect the samples within 60 days, if possible. Samples do not have to be collected on consecutive production days. The purpose of the follow-up sampling is to verify the effectiveness of the establishment's corrective and preventive measures. It is not necessary to sample consecutive lots to verify the effectiveness of these measures.

26. **Question:** For Alternative 1, FSIS suggests that when food contact surfaces are tested, and there are 3 consecutive positives, there should be intensified testing. What are Agency expectations regarding the nature of this intensified testing?

Answer: FSIS expects that whenever a FCS tests positive for *Listeria* spp., *Listeria*-like organisms, or *L. monocytogenes*, that the establishment would take immediate steps to determine the source of the positive test result, take corrective action, and verify the effectiveness of the corrective action in eliminating the source of the contamination. To accomplish this objective, the sampling and testing regime would likely be more extensive, i.e., "intensive," than whatever occurs on a routine monitoring basis.

27. **Question:** For Alternative 2, with only a post-lethality treatment, if the retest of the food contact surface is positive, corrective action is repeated until samples are negative – there is no requirement for intensified testing as for Alternative 1, which involves use of both a post-lethality treatment and an antimicrobial agent or process. This would appear to be a less stringent approach than for Alternative 1. Are these examples written as the Agency intended?

Answer: For Alternative 1, intensified testing is suggested if there are two consecutive positives. FSIS did not intend for the there to be unlimited testing in the case of Alternative 2 products/processes. FSIS anticipates that, absent an establishment demonstrating a science-based alternative, intensified testing likely will be conducted after 2 consecutive FCS positives for Alternative 1, 2 consecutive positives for Alternative 2 and Alternative 3 – non-deli/hot dog, and after one positive for Alternative 3 deli/hot dog.

28. **Question:** How many samples, which locations, and how frequently should samples be taken as follow-up to show that corrective actions have been effective?

Answer: This depends on the specific process and plant and the location of the positive site that is being "corrected." Sampling frequency is expected to be higher for deli meats and hot dogs in Alternative 3 than for other products.

29. **Question:** Is a frequency testing of one time a year acceptable?

Answer: Each plant must decide and explain in their sanitation program why their frequency of testing food contact surfaces is sufficient to ensure effective control of control *L. monocytogenes*. A minimum testing frequency of once a year is recommended in the Compliance Guidelines for products produced according to Alternative 1. Historical data that includes testing is one means to support the frequency of testing.

INSPECTION ACTIVITIES

30. **Question:** For Alternative 1, FSIS is not requiring establishments to have a testing program for food contact surfaces (FCS); however, the Agency recommends such testing at least twice a year. What actions would the Agency anticipate taking (e.g., enhanced verification testing) if a plant does not incorporate this testing in its program?

Answer: The recommended testing of FCS under Alternative 1 is for periodic verification that the post-lethality treatment is not challenged with

a level of *L. monocytogenes* that the post-lethality treatment was not designed to eliminate or reduce. Absent that verification, FSIS could verify that the HACCP plan ensures elimination or reduction of *L. monocytogenes* regardless of the level of testing. If inspection program personnel have questions about the establishment's response, they should contact their frontline supervisor or the TSC.

31. **Question:** When sampling plans are required for food contact surfaces (FCS), there is a requirement for an "explanation of why the testing frequency is sufficient." What are the criteria surrounding this required "explanation?" Who decides whether the establishment's "explanation" is adequate?

    Answer: The Agency expects that the establishment be able to articulate its thought process as to why it selected a particular frequency. Evidence, such as scientific articles or prior history, could be used, as well as practical considerations such as laboratory capacity, timing and cost/benefit analysis. Should there be an issue involving the "adequacy" of the explanation, inspection program personnel generally are directed to contact their front line supervisor or the TSC with specific questions. In addition, if warranted, in-plant inspection personnel can also use the expertise, skills, and knowledge of the CSO in determining whether the establishment's control system is in compliance with the regulatory requirements.

32. **Question:** Are there situations in which inspection program personnel may submit an inspector-generated sample?

    Answer: Yes, there may be situations in which inspection program personnel may feel that it is necessary to request permission to collect an inspector-generated sample. For example, an establishment produces a deli meat product under Alternative 2. Inspection program personnel observe that the establishment has modified the production process for this product, and it no longer uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. The product is now covered by Alternative 3, but the establishment has not modified its sanitation and testing program according to 430.4(b)(3)(iii) to reflect this change. In this situation, after consulting with their frontline supervisor to obtain permission to collect the sample, inspection program personnel are to obtain form FSIS 10,210-3, "Requested Sample Form," through channels from the Office of Public Health and Science prior to collecting a "for cause" sample. Remember, inspection program personnel must consult with their frontline supervisors before taking any inspector-generated samples.

33. **Question:** If inspection program personnel have not received a sample

request form in a number of months, should they take inspector-generated samples?

Answer: No, inspector-generated samples should not be submitted solely because the inspector has not received a generated sample request in the past few months. In its sampling programs, FSIS is concentrating its resources on those establishments that have chosen Alternative 3. Consequently, there will likely be times when certain products and facilities following Alternative 1 or Alternative 2 will be sampled less frequently than they have been in the past.

34. **Question:** If an establishment is using sliced deli meats or hot dogs as ingredients of a multi-component product such as a frozen meal, dinner, entree, or open-faced hot sandwich, are the finished products or in-process deli-meats or hot dogs subject to the verification testing program?

Answer: Yes, if the products are RTE.

35. **Question:** What is the importance of food contact surface testing for products that receive a post- lethality treatment that has been validated to destroy any *L. monocytogenes* that might be present?

Answer: The FSIS public health focus is on products that have a greater likelihood of becoming contaminated after the lethality step and on products that support the growth of *L. monocytogenes*. Since products that receive a post-lethality treatment that has been validated to be effective under the operational conditions in the establishment are unlikely to become further contaminated, the establishments that produce these products need not frequently test food contact surfaces or the environment where these products are produced. However, as noted in response to Question **XX**, testing of food contact surfaces serves to ensure that the effectiveness of the post-lethality treatment is not reduced by an excessive level of *L. monocytogenes*.

36. **Question:** What are the criteria regarding needs for corrective action for Alternatives 1, 2, and 3?

Answer: Guidelines for specific criteria for corrective action are described in the FSIS Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products. Corrective actions are to be followed up by targeted testing to verify that the corrective actions were effective.

37. **Question:** Paragraph 430.4(b)(3)(ii)(C) of the interim final rule allows for the release of product (i.e., deli meat and hotdog) placed on hold using a "sampling method and frequency that will provide a level of statistical

confidence that assures that each lot is not adulterated." What is meant by a "level of statistical confidence"? Is this based on the cases of sampling plans classified by the International Commission on Microbiological Specifications for Foods (ICMSF)?

Answer: FSIS recognizes the limitations of any sampling and testing plan to ensure product safety with 100% confidence. FSIS recognizes that the lower the likelihood of contamination, e.g., <1%, the higher the number of samples required to obtain a high degree (e.g., 95%) of confidence that the pathogen is absent from the sampled lot. Furthermore, FSIS recognizes that statistical sampling is not relevant to environmental sampling and testing, and that repeated sampling and testing of the environment is the best method to determine whether corrective actions (e.g., enhanced cleaning and sanitation) have been effective in eliminating potential harborage of any contamination. Although the agency will not dictate any particular sampling plan with regard to lot release following a positive FCS finding, historically, FSIS has recognized the use of ICMSF sampling plans for release of product. Under an ICMSF sampling plan, the number of samples would be dictated by the "case." Case 13 (n (number of samples)=15, c (number of samples that can be positive) =0) applies if conditions reduce the hazard (e.g., the product will be cooked or contains an inhibitor that would kill *L. monocytogenes* contamination); Case 14 (n=30, c=0) applies if the conditions cause no change in the hazard (e.g., the product is frozen or shelf stable); and Case 15 (n=60, c=20) applies if conditions may increase the hazard (e.g., the product is refrigerated and supports growth of *L. monocytogenes*).
The Compliance Guidelines provide a table for these sampling plans. The establishment could also contact a trade association, processing authority, or statistician for a testing frequency that ensures effective control of *L. monocytogenes* or indicator organisms.

38. **Question:** Based on the Compliance Guidelines, it appears that under Alternative 3, hold and test procedures must be conducted for hot dogs and deli meats after a second positive test on a FCS (following an initial positive and corrective action), whereas for other products under this Alternative, hold and test must occur after 3 consecutive positive food contact surface tests. Is this correct?

Answer: The interpretation relative to Alternative 3 and hot dogs and deli products is correct, i.e., hold and test procedures must be conducted after a second positive on a FCS. However, for all other products, there is no magic number; rather, the establishment is free to select at what point hold and test will be initiated, provided it can be justified.

39. **Question:** If an establishment employs hold and test procedures, how would FSIS define the "lot" to be held?

Answer: The definition of lot found in the FSIS Directive 10,240.4.The establishment, not the Agency, defines a production lot, but as noted in the definition, it is usually from clean up to clean up.

40. **Question:** If a positive result came from a product that was in a common cooler, would the whole cooler be considered a common lot?

Answer: No, but establishment might want to check other product that may have been close to affected product for cross contamination.

41. **Question:** What *Listeria* test data must be shared with FSIS personnel?

Answer: A description of the *Listeria* Control Program and associated data from monitoring and follow-up sampling are required to show that the program is effective. Any extra sampling data outside of this program may be shared with FSIS personnel at the establishment's option but is not required. FSIS believes that any decision-making data relative to the production of meat and poultry products is required to be made available to FSIS, particularly if the decision-making documentation affects the safety of the product. *Listeria* Control Program data must be available for 2 years.

42. **Question:** When will the Agency take samples?

Answer: FSIS will collect food contact surface and environmental samples during processing. The Agency will not notify the establishment for this sampling. CSO's may be asked to do the sampling. FSIS will also collect product samples after the pre-shipment review for pathogen testing. The CSIs will inform the establishment before collecting samples.

43. **Question:** If plant is three hours into operation and USDA comes to take a RTE sample this could produce a large amount of product to hold.

Answer: The establishment is not required to hold product when FSIS takes samples for product or environmental testing However, if the sample tests positive for *L. monocytogenes*, the establishment must recall the affected product. The amount of product held, or possibly subject to recall, is the entire lot of product from which the sample was selected. A lot is usually defined as that produced from cleanup to cleanup.

44. **Question:** Will USDA CSO's reassess plants for *Listeria* like they did for *E. coli* O157:H7?

Answer: They may, this is still under consideration.

HACCP/SANITATION SOP/PRE-REQUISITE PROGRAMS

45. **Question:** In the rule, FSIS states that if an establishment has implemented a post-lethality treatment, it must be included in the HACCP plan. If the establishment has data to demonstrate that *L. monocytogenes* is not a hazard reasonably likely to occur, must the post-lethality treatment be considered a CCP? Could an establishment include the treatment in a prerequisite program accessible to FSIS via the hazard analysis?

    Answer: It is conceivable that if the establishment can support its determination that *L. monocytogenes* is not reasonably likely to occur, without any reference to the post-lethality treatment, then the establishment would not be required to include such step as a CCP in its HACCP plan. However, FSIS would be interested in the establishment's justification for having the post-lethality treatment if it is unnecessary for *Listeria* control.

46. **Question:** What manner of monitoring (when, where and how temperatures are taken) of the post lethality treatment will the Agency find acceptable?

    Answer: FSIS will not dictate the monitoring and verification procedures for post-lethality treatments. That is the responsibility of the individual establishment.

47. **Question:** Although the rule allows flexibility in where control measures are written in the food safety system (especially with respect to antimicrobial agents/processes), the rule requires that establishments have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur if it selects to incorporate the control measures in its sanitation SOPs or prerequisite program, rather than in its HACCP plan. What are the evaluation criteria inspection personnel will use in determining whether the documentation is sufficient?

    Answer: Inspection program personnel determine whether the establishment has documented its decision making in the hazard analysis as to why the *Listeria* control program was placed in a prerequisite program. In addition, inspection program personnel verify that the HACCP plan, hazard analysis, sanitation SOP, and prerequisite programs meet regulatory requirements. If certain questions arise that are beyond their expertise, inspection program personnel generally are directed to contact their front line supervisor or the TSC.. In addition, if warranted, in-plant inspection personnel can also use the expertise, skills, and knowledge of the CSO in determining whether the establishment's control system is in compliance with the regulatory requirements.

48. **Question:** When measures for addressing *L. monocytogenes* are included in a prerequisite program other than an SSOP, the establishment must ensure that the program is effective and "does not cause the hazard analysis or the HACCP plan to be inadequate." Likewise, in the compliance guidelines, FSIS indicates that the establishment must verify that the antimicrobial program is effective, and "that it does not cause the hazard analysis or the HACCP plan to be inadequate." What does the Agency mean by this?

Answer: An effective prerequisite program will reduce the likelihood of occurrence of a hazard. Based on such a program, an establishment could deem a hazard not reasonably likely to occur in its hazard analysis and need not adopt a CCP for the hazard. However, if the prerequisite program is not effective (or is not being followed), it means the hazard may become reasonably likely to occur. In such a case, the HACCP plan would be inadequate, since it does not include a CCP for the hazard. Accordingly, FSIS expects that establishments will routinely assess the effectiveness of the prerequisite programs and make any necessary adjustments to ensure that *L. monocytogenes* does not become a hazard reasonably likely to occur.

49. **Question:** What information is needed in the SSOPs to explain how food contact surfaces are kept sanitary and free of *L. monocytogenes*?

Answer: FSIS expects the same degree of detail than that currently included in the establishment's Sanitation SOP, provided that the specific sanitation requirements of the regulation are addressed either in the Sanitation SOP or other specific program regarding *Listeria* control.

50. **Question:** How do USDA laws apply to inspected retail exempt product?

Answer: Through adulterated products.

51. **Question:** Can partially cooked and fully cooked product be produced in the same room?

Answer: Yes. However, the HACCP plan and Sanitation SOP should include the procedures used to prevent cross contamination of the fully cooked product.

VALIDATION/VERIFICATION

52. **Question:** Are there specific requirements (e.g., log-reductions) for validating the efficacy of post-lethality treatments, antimicrobial agents,

and antimicrobial processes?

Answer: FSIS has chosen not to establish specific requirements, allowing the establishments to select the appropriate levels based on their operations and the product's expected shelf life and use. However, FSIS would anticipate that the establishment will have documentation to support its actions and conclusions. On post-lethality treatments, FSIS expects the establishment's HACCP documentation would demonstrate that the post-lethality treatment will be adequate to reduce a level of contamination that has a potential to occur before packaging. For antimicrobial agents and processes, the agency expects that there will not be a significant increase in numbers of organisms during the product's shelf life to a level resulting in a public health risk, as well as detectable levels of the pathogen.

53. **Question:** In Table 1 "Summary of final rule requirements by establishment group," group #2 (68 FR 34229), do items 5 and 6 (validation and verification) apply when freezing is used as the antimicrobial process? (i.e., Is validation of freezing effectiveness required and must an establishment demonstrate effectiveness of freezing in controlling *L. monocytogenes* on an ongoing basis?)

Answer: On validation, pursuant to 9 C.F.R. §§ 417.2 & 417.5 of the HACCP regulations, an establishment must have its decision-making documents as to whether a food safety hazard is likely to occur. Since freezing is a well-recognized bacteriostatic process, an establishment would not need extensive scientific support. As to verification, many establishments include freezing as a CCP for stabilization (cooling of product). The continuing verification for this CCP could be used to verify the effectiveness of the bacteriostatic process. If freezing is not a CCP in a HACCP plan, FSIS would expect some verification activities to demonstrate that the product is indeed being frozen below the level which the scientific validation documents establishes as having the bacteriostatic effect.

54. **Question:** What records would the agency require for products with formulations that are inherently antilisterial but that may not be formulated specifically for that purpose but rather to achieve the desired product characteristics (e.g., BBQ and pickled meats, precooked bacon, beef snack sticks)? Would the establishment be required to make changes to the HACCP plan to account for the antilisterial benefit of the formulation/process?

Answer: As to the records that would be required to substantiate the antilisterial properties of a product formulation, FSIS would expect that the

establishment would have scientific support for the conclusion that the nature of the product, as manufactured by the establishment, has such an effect, e.g., citations to published data. As to inclusion in the HACCP plan, that would only be required for a post-lethality treatment (see below). If the post-lethality listericidal effect is based solely on the product characteristics, the agency would expect that the process of achieving the characteristics would be incorporated in the HACCP plan.

55. **Question:** Can you give an example of information that validates diacetate in a RTE product?

Answer: Information that validate diacetates in product can be found in scientific journals such as the Journal of Food Protection and Meat Science. Summaries of some studies on diacetates and their references are included in the Compliance Guidelines.

56. **Question:** Can establishments use the studies cited in the Compliance Guidelines for verifications as they do for the Compliance Guidelines in Appendices A and B in the final rule for certain meat and poultry products?

Answer: Yes, provided the processing procedures and ingredients are equivalent to those in the studies. For example, if the pH and concentration of antimicrobial in the study were both considered critical, then the product must have that pH and contain the antimicrobial in the concentration used in the study.

READY-TO-EAT VERSUS NOT-READY-TO-EAT

57. **Question:** The interim final rule only applies to ready-to-eat (RTE) products. Will the provisions in Directive 10.240.3 (Attachment 2) still apply in distinguishing between RTE and not-ready-to-eat (NRTE) product? How will the agency classify products containing both raw and cooked ingredients?

Answer: The table that shows what constitutes a RTE product will be carried forward in the new directive. Under the directive, products containing both raw and cooked ingredients (e.g., a frozen entrée containing blanched vegetables and fully cooked meat) will <u>not</u> be considered RTE if: (1) the product label prominently indicates the need to cook the products for safety, <u>and</u> (2) there are validated cooking instructions.

58. **Question:** Does the agency intend to require all products considered NRTE to bear safe handling instructions in addition to validated cooking

instructions (for example, a partially cooked frozen dinner)?

Answer: A safe handling statement would be required if the meat or poultry component is NRTE. If the non-meat component requires cooking for safety, the safe handling statement is not required but is encouraged.

59. **Question:** Are frozen foods to be cooked by the consumer considered to be RTE?

Answer: A frozen product to be cooked may be either RTE or NRTE. FSIS distinguishes between RTE and NRTE foods in Attachment 2 to the new directive.

60. **Question:** Does partially cooked product have to comply with *L. monocytogenes* control measures?

Answer: Partially cooked or not fully cooked products are not RTE products and are not covered by the rule. E.g. a not fully cooked ham.

61. **Question:** Would Country Cured Hams have to comply with *L. monocytogenes* control measures?

Answer: If the country cured ham was labeled as RTE, it would have to comply with the regulation.

62. **Question:** Is a frozen RTE sausage patty applicable to the Alternatives?

Answer: Yes, if it is post-lethality exposed.

63. **Question:** Why does 319.180 not cover bratwurst?

Answer: 9 CFR 319.180 covers RTE cooked sausages such as hotdogs. Bratwurst is covered under 319.140.

POST –LETHALITY TREATMENT

64. **Question:** The June 6, 2003 Interim Rule defines a post lethality treatment as "a lethality treatment that is applied or is **effective** after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure." The lethality treatment for dried meat snacks results in a low water activity [<0.85] which is still **effective** after the product is packaged and not only suppresses *L. monocytogenes* growth but can cause *L. monocytogenes* death. How does FSIS view <0.85 water activity as a post lethality treatment?

Answer: Since products with water activity less than 0.85 will not support the growth of *L. monocytogenes* and can sometimes even cause *L. monocytogenes* death, FSIS will consider water activity of <0.85 at the time the product is packed to be a post-lethality treatment if there is a listericidal effect in the specific product and the establishment has documentation that the intended effect occurs prior to distribution of the product into commerce. The level of pathogen reduction necessary to result in a safe, unadulterated product, based on the expected highest level of post-lethality contamination, also would need to be included as part of the support documentation. FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve lethality of *L. monocytogenes* such that greater than 2 $\log_{10}$ reduction occurs, FSIS would view this process as more protective than one providing less lethality.

65. **Question:** As noted above, many dried meat products not only do not support the growth of *L. monocytogenes* but *L. monocytogenes* present on the product will die. If challenge studies are conducted to prove the death of some identified amount of *L. monocytogenes*, will FSIS consider the products to fall under Alternative I?

Answer: When challenge or inoculation studies show death of *L. monocytogenes* during shelf life and are incorporated into the establishment's HACCP plan, those products likely will fall under Alternative 1.

66. **Question:** FDA has established in the Food Code a definition for foods that are not "potentially hazardous". In the May 1999 "*Listeria* Guidelines for Industry" [text included in footnote][*] FSIS quoted the FDA Food Code

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[*] Currently available information indicates that establishments should view a RTE meat or poultry product as a food that supports the growth of *Listeria monocytogenes* unless the 1999 Food Code (DHHS, U. S. Public Health Service, FDA) excludes the product from its definition of a "Potentially hazardous food" (excerpts) because (1) the product has an a_w value of 0.85 or less; (2) the product's pH is 4.6 or below when measured at 24°C (75°F); (3) a food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution; (4) laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *C. botulinum* can not occur, and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or (5) the product does not support the growth of microorganisms..."

guidelines for industry to use when assessing the hazards of *Listeria*. If meat/poultry products meet one or more of the definition criteria, the product is not a potentially hazardous food. How will FSIS use these criteria to determine the appropriate Alternative?

Answer: Merely because a product is not "potentially hazardous" under the Food Code will not be definitive in terms of the appropriate classification. The Food Code definition could include products meeting the processing requirements of Alternatives 1 and 2. FSIS will look to whether a process has a listericidal effect, and whether the growth is suppressed to determine the classification within the appropriate Alternatives outlined in the regulation.

67. **Question:** Would the use of infrared (IR) technology on slicing logs be considered a post-lethality treatment? If the IR is applied immediately before the slicer, is this close enough to the final product packaging to qualify as a post-lethality treatment?

Answer: Although such treatment would assist in controlling any contamination before the slicer, since the slicer itself may become contaminated from a source other than the product, this contamination could be conveyed onto the product. In order to be considered as a post-lethality treatment, the product could not be exposed to the post-processing environment after the treatment.

ANTIMICROBIAL AGENT OR PROCESS

68. **Question:** The June 6, 2003 Interim Rule defines an antimicrobial agent as "A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product." Does FSIS require a specific concentration of inhibitor to qualify as an antimicrobial agent?

Answer: There is no "required" percentage. It is up to the establishment to determine which inhibitors to use and at what amount to maintain quality while enhancing safety. However, the establishment must validate that the antimicrobial agent has an inhibitory effect on the growth of *L. monocytogenes* and maintains that effect throughout the shelf life of the product. Generally, inhibiting growth of *L. monocytogenes* to less than 1 $\log_{10}$ of growth throughout the product shelf life would be considered effective.

69. **Question:** Starter cultures or vinegar, used in product manufacturing or directly in formulations, will result in products with a pH <4.6 [creating a product that is not "potentially hazardous" per the FDA Food Code]. How does FSIS view the use of a starter cultures and vinegar as antimicrobial agents?

Answer: FSIS will consider starter cultures or vinegar as antimicrobial agents if the addition of the starter culture or vinegar results in a finished product with a pH of <4.6, and the establishment documents that this pH level in the specific product suppresses/limits growth.

70. **Question:** Could cure (156 ppm added nitrite) be considered an antimicrobial agent?

Answer: Sodium nitrite as an antimicrobial agent is primarily used to inhibit *Clostridium botulinum* growth and toxin production in cured meats. A study has shown an inhibitory effect of nitrite, salt, and vacuum packaging on *L. monocytogenes* growth in fish. The establishment would have to provide documentation on the inhibitory effect of nitrite on *L. monocytogenes* in meat and poultry and indicate what other factors, such as salt concentration, are critical for the inhibitory effect.

71. **Question:** The June 6, 2003 Interim Rule defines an antimicrobial process as "suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product." Many dried meat products undergo processes, such as fermentation and/or drying, that create inherent product characteristics [pH<4.6, water activity<0.85] that do not allow growth of *L. monocytogenes* during shelf life. Will FSIS view the use of fermentation and drying processes as antimicrobial processes?

Answer: Fermentation and drying will be considered antimicrobial processes if they result in finished product with pH or water activity that suppresses or limits the growth of *L. monocytogenes*. If this "process" is also listericidal during the shelf life of the product, it could also serve as a post-lethality treatment.

72. **Question:** On page 18 of the Guidelines (second bullet), FSIS states that "antimicrobials used in the formulation must have an effective antilisterial activity throughout the commercial shelf life of the product." What is meant by this statement? The preamble to the interim final rule states that the effect of freezing could only continue throughout the shelf life of the product if the product were maintained continuously in the frozen state. Would a frozen product that is thawed under refrigeration just prior to use thus be excluded from the definition of an antimicrobial process?

Answer: The requirement that an antimicrobial process or product formulated with an antimicrobial suppress or limit growth throughout the commercial shelf life means that an establishment must have validated that the process or formulation does what is claimed. These validation records must be available to FSIS. The requirement that a product remain frozen throughout its shelf life is intended to exclude situations where a product is distributed frozen and then thawed and sold as a refrigerated product. If the product is thawed as part of the preparation process, the product will be deemed to have been frozen throughout its shelf life.

73. **Question:** The Compliance Guidelines mention the possibility that an antimicrobial process could serve as both a post-lethality treatment and a growth inhibitor. Formulated products that are shelf stable, such as country cured ham and pepperoni, are mentioned as examples. Does the Agency have any examples for non-shelf stable products? Are there circumstances under which freezing could serve both as a post-lethality treatment and antimicrobial process, which would allow product to fall under Alternative 1?

Answer: At this time, the Agency does not have a particular product in mind. The question is whether the processing/formulation of the product is such that it continues to inhibit and reduce/eliminate organisms. If an establishment can demonstrate such an effect through freezing (either through scientific articles or laboratory studies), FSIS would deem freezing as a post-lethality treatment. However, FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve suppression of *L. monocytogenes* such that growth can be more than 2-logs during shelf life, FSIS will likely not consider this to qualify as a growth inhibitor for Alternative 2. Likewise, if the post-lethality treatment achieves less than 1 log reduction, FSIS will likely not consider this to qualify as a post-lethality treatment for Alternative 1 or 2.

74. **Question:** Can a RTE product with a water activity of 4.8% be acceptable for an Alternate?

Answer: Water activity is not expressed as a percent. Water activity can range from 0.2 for milk powder to 0.98 or greater for meat and poultry. A product with a water activity of 0.85 is usually considered shelf stable and would not support the growth of *L. monocytogenes*. pH also is not expressed as percent and ranges from 1 to 14. A pH of 4.8 may or may not inhibit the growth of *L. monocytogenes*. This would have to be validated for the particular product.

75. **Question:** Is there any other anti microbial agent besides Sodium

Lactate/Diacetate that can be used?

Answer: These are the two antimicrobial agents that research studies have shown to be effective in suppressing L. monocytogenes growth when added to the formulation of RTE meat and poultry products. There are others whose application in meat and poultry are still being researched.

ALTERNATIVES

76. **Question:** Will definitions for Low Risk products be applicable?

Answer: "Risk" categories as used in the previous directive have been deleted. After October 6th, establishments must choose Alternates 1-2 or 3 for RTE products.

77. **Question:** Alternative 1 and 2 look the same to me, please explain.

Answer: Alternative 1 uses two control methods: 1) a post-lethality treatment that eliminates or reduces *L. monocytogenes*; and 2) an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* throughout the shelf life of the product.

Alternative 2 uses only one of the control methods mentioned above. A product in Alternative 1 has the lowest risk of *L. monocytogenes* contamination because it uses 2 control methods, followed by a product in Alternative 2, which has a medium risk. A product in alternative 3 has the highest risk because it does not use any of these control methods.

78. **Question:** Does a ham product cooked in an impermeable bag have to comply with one of the three RTE Alternatives?

Answer: If the ham is not removed from the impermeable bag after cooking nor repackaged before shipping, then it is not post-lethality exposed and not subject to the *Listeria* rule. If it is removed from the cooking bag and repackaged, then it is subject to the rule because it was post-lethality exposed..

79. **Question:** Would further processing of a RTE ham (slicing) have to comply with Lm Control measures?

Answer: Yes, this would be applicable to the RTE Alternatives. The entire process is considered, whether it involves formulation to packaging or just slicing and packaging.

80. **Question:** Is a ham a lower risk if unsliced? Is it a different risk factor?

Answer RTE fully cooked ham that is removed from the cooking bag and repackaged, whether sliced or unsliced is post-lethality exposed.

81. **Question** Can a UV light be used as an intervention on RTE product?

Answer: If the establishment can validate that the process eliminates, reduces or suppresses *L. monocytogenes*, it can be used as a control method.

82. **Question:** What is the FSIS sampling frequency for Alternative 2?

Answer: No, frequencies are yet to be established by USDA.

83. **Question:** If a product is made under Alternative 2 or 3, and there is a positive L. monocytogenes sample, how many more samples would be required taken by USDA?

Answer: The Agency does not require a set number of samples rather the establishment must test at a frequency that provides a level of statistical confidence ensuring the lots tested are not adulterated with *L.. monocytogenes*.

84. **Question:** Can an establishment fall under more than one Alternative?

Answer: FSIS recognizes that establishments may be producing products under different Alternative control programs. These various products may best be covered in individual HACCP plans, though an establishment is free to adopt whatever program can best enable compliance.

85. **Question:** If plant wants to change Alternative, can they?

Answer: Yes, if the establishment changes the production process to meet the requirements for the particular Alternative. For example, if an establishment employs only sanitation procedures to control *L. monocytogenes* (Alternative 3) but later uses an antimicrobial agent or process, it would then have to meet the requirements for Alternative 2. Establishments are encouraged to use antimicrobial agents or post-lethality treatments if possible in order to reduce the risk of *L. monocytogenes*.

86. **Question**: Can there be two Alternatives within a single HACCP plan?

Answer: Once again, the decision can be made by the establishment. Products are grouped in a single HACCP plan when the hazards, CCPs, and critical limits are essentially the same, provided that any required

features of the plan that are unique to a specific product are clearly delineated in the plan and observed in practice. Thus, a single HACCP plan could cover hot dogs formulated with and without antimicrobial agents (Alternative 2 and Alternative 3), provided that the HACCP plan clearly distinguishes any critical differences.

87. **Question:** Some establishments produce multiple types of products on the same line. Will the agency require that the control program, including sampling and test and hold procedures, be the same for all products produced on the line under Alternatives 2 and 3 even though product characteristics differ?

Answer: The Alternatives presented in the interim final rule are based on the relative risk posed by various products depending on their characteristics and ordinary preparation practices. If an establishment uses the same FCS on the same production day (clean-up to clean-up) for products falling within two Alternatives, the products would be treated as if they were in the higher risk category with respect to environmental sampling. However, with respect to hold and test procedures, the number of samples tested would be related to product risk (see question # 40).

88. **Question:** Is it possible for a multi-product plant to use all three RTE Alternatives?

Answer: Yes.

89. **Question:** On the topic of FSIS verification, the Rule states that different options will bring different levels of scrutiny. What about situations in which a plant's production is mixed, i.e. the plant produces cured products with lactate and diacetate but also produces non-cured products without this anti-microbial agent and would rely solely on sanitation practices for the non-cured product? Assuming that the plant's tonnage is evenly split between the two, how does FSIS structure its scrutiny and verification?

Answer: FSIS scrutiny and verification are based primarily on the risk categories of the products. As discussed above, if an establishment produces products using two (or three) Alternative control programs, the agency's focus will be on product manufactured under Alternative 3, then 2, then 1.

90. **Question:** Would frozen RTE products (entrees, chicken nuggets, turkey franks) fall under Alternative 2? What about other products that are processed in a manner that suppress growth?

Answer: Freezing would be considered as suppressing the growth of *L.*

monocytogenes provided the product is frozen after processing and maintained in a frozen state throughout the product shelf life (e.g. not slacked prior to retail sale). If the product was slacked prior to retail, the establishment could not consider the product as meeting the requirements of Alternative 2 and most likely would have to handle the product according to Alternative 3. Product pH (antimicrobial agent) or drying (antimicrobial process) are other methods of commonly used to suppress or prevent the growth of *L. monocytogenes* in products such as salami and jerky, respectively.

91. **Question:** Alternative 2 includes products that receive a post-lethality treatment or an antimicrobial agent or process. Does this category include other products that do not support the growth of *L. monocytogenes*?

Answer: Alternative 2 includes all products that receive a post-lethality treatment or use an antimicrobial agent or process to prevent or limit the growth of *L. monocytogenes* throughout the shelf life of the product,The post-lethality treatment must be included in the establishment's HACCP plan but the antimicrobial agent or process can be documented in the HACCP plan, Sanitation SOP, or other prerequisite program.

PRODUCTION VOLUME

92. **Question:** FSIS expects establishments to provide production volume and other information on a form that will be electronically available after the rule becomes effective. What are the Agency's expectations as to when this form must be submitted?

Answer: The form is currently under review pursuant to the Paperwork Reduction Act and is not available. FSIS will provide establishments with adequate time to provide the information, at least 30 days before submission.

LABELING

93. **Question:** Both the preamble to the rule and the compliance Guidelines provide examples of validated claims that would be permitted on product labeling. In all cases, the labeling claim is for "X added to prevent the growth of *L. monocytogenes*." Would claims such as "X added to enhance product quality and safety," be permissible?

Answer: The agency will be amenable to any claim that identifies the substance being used, the benefits of the substance, and why it has been used. The claim must be specific, however, to *Listeria* control, and it

should be limited to safety and not quality attributes. However, FSIS is identifying criteria that it will tentatively use to assess risk-based verification activity. Generally, if establishments achieve suppression of *L. monocytogenes*, but growth can be 1-$\log_{10}$ or more during shelf life, FSIS may not consider this to qualify as a growth inhibitor for a claim.

94. **Question** Must the establishment resubmit labels when adding diacetate?

Answer: The establishment can submit generic label as long as diacetate is added in the ingredient listing. If there is a labeling claim on enhanced protection due to the use of diactates, labels must be submitted for approval.

95. **Question:** RTE product that will go to a restaurant to be cooked again, should it have cooking instructions on it?

Answer: Yes.

GENERAL

96. **Question:** How does the agency plan to ensure uniform interpretation of company records, agency policy, and implementation of enforcement actions by FSIS inspection personnel?

Answer: As a result of training and supervision, FSIS attempts to achieve uniform interpretation of regulatory requirements. However, because of the scientific basis of the interim final rule, the Directive likely will specify that should the in-plant inspector have any questions as to an establishment's *Listeria* control program, inspection program personnel are to go through supervisory channels with specific questions. In addition, if warranted, in-plant inspection personnel can also use the expertise, skills, and knowledge of the CSO in determining whether the establishment's control system is in compliance with the regulatory requirements.

97. **Question:** Must Export products meet these RTE requirements?

Answer: All RTE products must meet USDA requirements.

98. **Question:** Is retail exempt or custom exempt applicable to the RTE rules?

Answer: They are not applicable but he USDA inspector must be informed that product is exempt before the product is formulated. There would be no inspection at retail.

99. **Question:** Will these RTE results be released under the Freedom of Information Act?

Answer: Results from FSIS sampling can be released under the Freedom of Information act.